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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,705	02/21/2002	John Barthelow Classen	22499-68466	1273

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EXAMINER

LEROUX, ETIENNE PIERRE

ART UNIT PAPER NUMBER

2161

DATE MAILED: 03/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/081,705

Applicant(s)

CLASSEN, JOHN BARTHELOW

Examiner

Etienne P LeRoux

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 February 2006.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 201-213 and 215-246 is/are pending in the application.
- 4a) Of the above claim(s) 33-41, 46-63 and 247-249 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 201-213 and 215-246 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>2/2/06</u> . | 6) <input type="checkbox"/> Other: _____ |

Election/Restriction

If after an office action on an application, the applicant presents claims directed to an invention distinct from an independent of the invention previously claimed, the applicant will be required to restrict the claims to the invention previously claimed if the amendment is entered, subject to reconsideration and review, refer 37 CFR 1.145.

A telephone call was made to Ms Evelyn McConathy on March 13, 2006 to request an oral election. Claims 201-246 were elected, without traverse, for examination on the merits.

Claim Status:

Claims 201-213 and 215-246 are pending. Claims 1-32, 42-45 and 64-200 are cancelled, claims 33-41 and 46-63 and 247-249 are withdrawn and claim 214 is missing. Claims 201-213 and 215-246 are rejected as detailed below.

Claim Objections

Claims 215 through 246 are objected to because claim 214 has been omitted. Numbering of the claims needs to be addressed.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined

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application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 201 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 15 of U.S. Patent No 6,219,674 (Classen). Although the conflicting claims are not identical, they are not patentably distinct from each other because elements of claim 201 of instant application are fully covered by claim 15 of US Pat No 6,219,674.

Claim 15 of U.S. Patent No 6,219,674 (Classen) contains every element of claim 201 of instant application and thus anticipates the claim of the instant application. Claim(s) of the instant application therefore is/are not patentably distinct from the earlier patent claim(s) and as such is unpatentable over obvious-type double patenting. A later patent/application claim is not patently distinct from an earlier filed claim if the claim is anticipated by the earlier claim.

Instant Application:

Claim 201 recites:

A method for using data associated with at least one dataset, wherein essential adverse event information is stored, and

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wherein the data is derived from an analysis of data from at least one adverse event data source of previously gathered data, and

identifies at least one new useful characteristic or use for a product or device responsive to identification of at least one new essential adverse event associated therewith, wherein the database comprises stored essential adverse event information, and wherein the adverse event information includes the at least one new use or characteristic,

said method comprising commercializing new essential adverse event information stored therein.

US Pat No 6,219,674:

Claim 15 recites:

15. A method for creating and using product data, said method comprising the steps of:

accessing at least one adverse event data source that stores adverse event data associated with a commercially available product;

analyzing said adverse event data to identify new adverse events associated with the product;

creating at least one adverse event information database, said creating comprising analyzing data from said at least one adverse event data source to identify at least one new use for the product responsive to identification of at least one new adverse event associated with the product, said creating further comprising storing adverse event information, said adverse event information including said at least one new use; and

commercializing adverse event information stored at said at least one adverse event information database.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 201, 203, 205-207, 209-211, 216, 217, 220, 221, 225-228, 231-245 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat No 5,726,884 issued to Sturgeon et al (hereafter Sturgeon) in view of US Pat No 6,944,776 issued to Lockhart et al (hereafter Lockhart).

Claims 201 and 226:

Sturgeon as admitted prior art discloses:

A method for using data associated with at least one database, wherein essential adverse event information is stored and wherein the data is derived from an analysis of data from at least one adverse event data source of previously gathered data and identifies at least one new useful characteristic or use for a product or device responsive to identification of at least one new essential adverse event associated therewith, wherein the database comprises stored essential adverse event information, and wherein the adverse event information includes the at least one new use or characteristic [col 8, lines 23-25]

Sturgeon discloses the essential elements of the claimed invention as noted above but does not disclose said method comprising commercializing new essential adverse event information stored therein. Lockhart discloses commercializing new essential adverse event information stored therein [protected content 200, Fig 2, col 11, lines 10-30]. It would have been

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obvious to one of ordinary skill in the art at the time the invention was made to modify Sturgeon to include commercializing new essential adverse event information stored therein as taught by Lockhart for the purpose of selling information for profit [Lockhart, col 1, line 37].

Claim 203:

The combination of Sturgeon and Lockhart discloses the elements of claim 201 as noted above and furthermore discloses wherein the at least one adverse event data source comprises information regarding amount of use of the product or device or duration of exposure to the product or device by subjects [Sturgeon: col 8, lines 23-25]

Claim 205:

The combination of Sturgeon and Lockhart discloses the elements of claim 201 as noted above and furthermore discloses wherein commercializing further comprises selling, leasing or licensing the newly identified product information [Lockhart: col 1, line 47-48]

Claims 206, 227, 241 and 242 :

The combination of Sturgeon and Lockhart discloses the elements of claim 201 as noted above but does not disclose protecting the intellectual property interest in the newly identified product information. Official Notice is taken that protecting the intellectual property interest in the newly identified product information is well-known and expected data source to one of ordinary skill in the art because patents and patent applications include novel and non-obvious sources of data. The ordinarily skilled artisan would have been motivated to improve the disclosure of the combination of Sturgeon and Lockhart by considering data sources included in patents and patent applications for the purpose of ascertaining the current state of the art.

Claim 207:

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The combination of Sturgeon and Lockhart wherein commercializing further comprises formatting the data relating to at least one new adverse event associated with exposure to, or use of the product or device, or documenting same, such that a manufacturer or distributor of the product or device must inform consumers, or individuals responsible for the user, physicians or prescribers about at least one new adverse event associated with exposure to or use of the product or device [inherent in hazardous material management per the abstract]

Claim 209:

The combination of Sturgeon and Lockhart discloses the at least one adverse event data source comprises the at least one new use of the product or device is a restricted use in at least one population subgroup, when there is observed to be a high risk of at least one adverse event associated with exposure to or use of the product [Sturgeon: col 8, lines 23-28]

Claims 210, 228 and 243-245:

The combination of Sturgeon and Lockhart discloses the elements of claim 201/226/241 as noted above and furthermore discloses the new use is further identified as comprising restricting exposure of the product to one of the high risk associated groups selected from the group consisting of chemicals [Lockhart: col 8, lines 23-28]

Claim 211:

The combination of Sturgeon and Lockhart discloses the elements of claim 201 as noted above and furthermore discloses wherein the essential adverse event data is proprietary [Lockhart: col 1, lines 33-48]

Claims 216, 217, 220, 221:

The combination of Sturgeon and Lockhart discloses the elements of claim 201/210 as noted above and furthermore discloses wherein the product is non-medical [Sturgeon: col 8, lines 23-28]

Claims 231-234 and 238-240:

The combination of Sturgeon and Lockhart discloses the elements of claim 201 as noted above and furthermore discloses establishing a new safety data sheet for a commercially available product or device, wherein the safety data sheet identifies at least one new essential adverse event for the at least one product or device [Sturgeon: abstract].

Claim 235-237:

The combination of Sturgeon and Lockhart discloses the elements of claim 201 as noted above and furthermore, discloses using the essential information in a novel manner to produce higher return for development costs associated with the product [Lockhart, col 1, lines 45-50 and col 5, lines 30-45]

Claim 225:

The combination of Sturgeon, Lockhart and Portwood discloses the elements of claims 201 and 222 as noted above and furthermore discloses a proprietary new characteristic of, or use for, a product or device [Sturgeon, col 8, lines 23-28].

Claim 202 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Sturgeon and Lockhart and further in view of US Pat No 5,386,829 issued to Diamond (hereafter Diamond).

Claim 202:

The combination of Sturgeon and Lockhart discloses the elements of claim 201 as noted above but does not disclose wherein the at least one adverse event data source comprises adverse event data gathered from at least 5000 subjects. Diamond discloses a patient is selected from a population of 5000 [col 1, line 50 through col 2, line 58]. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Sturgeon and Lockhart to include wherein the at least one adverse event data source comprises adverse event data gathered from at least 5000 subjects based on the teaching of Diamond for the purpose of making allowance for the unfortunate fact that medical tests are not 100% reliable [Diamond: col 1, lines 26-50].

Claims 204 and 244 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Sturgeon and Lockhart and further in view of US Pat No 6,221,851 issued to Feldman (hereafter Feldman).

Claim 204:

The combination of Sturgeon and Lockhart discloses the essential elements of claim 201 as noted above but does not disclose wherein the at least one adverse event data source comprises information regarding product post-exposure adverse event data, which is recorded in selected time increments, ranging from less than one hour to more than ten years. Feldman discloses one hour and 5 years [Fig 2]. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Sturgeon and Lockhart to include wherein the at least one adverse event data source comprises information regarding

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product post-exposure adverse event data, which is recorded in selected time increments, ranging from less than one hour to more than ten years based on the disclosure of Feldman for the purpose of testing the drug over a long period in order to obtain accurate results.

Claim 244:

The combination of Sturgeon and Lockhart discloses the elements of claim 201 and 208 as noted above and furthermore discloses wherein the product or device is commercially available and further comprising identifying the new use as a restricted use in at least one population subgroup when there is observer to be a high risk of at least one adverse event associated with exposure to or use of the product or device [inherent in hazardous material management per the abstract]

Claim 208 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Sturgeon and Lockhart in view of Applicant's admitted prior art (AAPA).

Claim 208:

The combination of Sturgeon and Lockhart discloses the elements of claim 201 as noted above but does not disclose determining the value of commercializing the at least one new characteristic or use determined from the at least one identified adverse event. AAPA discloses determining the value of commercializing the at least one new characteristic or use determined from the at least one identified adverse event [paragraph 113]. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Sturgeon and Lockhart to include determining the value of commercializing the at least one new

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characteristic or use determined from the at least one identified adverse event based on AAPA for the purpose of determining how much to charge the customer for information contained in the database of adverse drug interactions [col 6, lines 55-65]

Claims 212, 213, 215, 218, 219, 229 and 230 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Sturgeon and Lockhart and further in view of US Pat No 5,950,630 issued to Portwood et al (hereafter Portwood).

Claims 212, 213, 218, 219, 229 and 230:

The combination of Sturgeon and Lockhart discloses the elements of claim 201/210/226 as noted above but does not disclose wherein the product is medical. Portwood discloses the product is medical [col 6, lines 55-67]. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Sturgeon and Lockhart to include wherein the product is medical as taught by Portwood for the purpose of verifying the patient's prescribed medicine [Portwood: col 10, lines 45-65].

Claim 215:

The combination of Sturgeon, Lockhart and Portwood discloses the elements of claims 201 and 212 as noted above and furthermore discloses wherein the medical product is a generic drug [Portwood: col 1, lines 50-55]

Claims 222-224, and 246 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Sturgeon and Lockhart in view of Pat No 6,097,995 issued to Tipton et al (hereafter Tipton).

Claims 222 and 223:

The combination of Sturgeon and Lockhart discloses the elements of claim 201/209 as noted above but does not disclose labeling notifying a user of at least one new essential adverse event for the product or device. Tipton discloses labeling notifying a user of at least one new essential adverse event for the product or device [Fig 100]. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Sturgeon and Lockhart to include labeling notifying a user of at least one new essential adverse event for the product or device as taught by Tipton for the purpose of reducing liability in the event of injury to a user.

Claim 224:

The combination of Sturgeon, Lockhart and Tipton discloses the elements of claim 201 and 222 as noted above and furthermore discloses a proprietary new characteristic of, or use for, a product or service [Sturgeon, col 8, lines 23-28]

Claim 246:

The combination of Sturgeon, Lockhart and Tipton discloses the elements of claim 201 and 222 as noted above and furthermore discloses a proprietary new characteristic of, or use for the product or device, wherein the product or device is commercially available, and wherein the new use comprises a restricted use in at least one population subgroup when there is observed to

be a high risk of at least one adverse event associated with exposure to or use of the product or device [inherent in hazardous material management per the abstract]

Response to Arguments

Applicant's arguments with respect to claims 201-246 have been considered but are moot in view of the new ground(s) of rejection necessitated by Applicant's claim amendments.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Etienne P. LeRoux whose telephone number is (571) 272-4022. The examiner can normally be reached Monday through Friday between 8:00 am and 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Safet Metjahic can be reached on (571) 272-4023. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Etienne LeRoux

March 15, 2006

A handwritten signature in black ink, appearing to read 'Etienne LeRoux', is written over the typed name and date.